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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/484,484

01/18/2000

Hubert Koster

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07/16/2002

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EXAMINER

WILSON, JAMES O

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 07/16/2002

is

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/484,484

Applicant(s)

Koster et al.

Examiner

Wilson, James D.

Group Art Unit

1623

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on April 16, 2002
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 6, 7, 9-11, 14-17, 20-22, 25, 26, 29, 31, 32, 39, 40, 45, 47-49 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 6, 7, 9-11, 14-17, 20-22, 25, 26, 29, 31, 32, 39, 40, 45, 47-49 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6, 7, 9-11, 14-17, 20-22, 25, 26, 29, 31, 32, 39, 40, 45 and 47-49 are provisionally rejected under the judicially created doctrine of double patenting over claims 5-9, 27-40 and 45-49 of copending Application No. 09/067,337. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application

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since the referenced copending application and the instant application are claiming common subject matter, as follows:

Determining the scope and contents of the prior art

Each of the following sets of claims, specifically claims 6, 7, 9-11, 14-17, 20-22, 25, 26, 29, 31, 32, 45 and 49 of 09/484,484 and 5-9, 27-33, 45-46 and 49 of copending application 09/067,337 the application are all drawn to a liquid phase carrier (LPC), all being drawn from the same structural formulae designated by the structures Ia, Ib, Ic, Id, Ie, If, IIa, IIb, IIc and IId and the structures set forth in each application's claim 45. The substantial overlap in structure and intended modifications to the core of said structures do indeed represent subject matter covered by both application's claims. Likewise, the following sets of claims are drawn to the synthesis of a solution phase biopolymer using LPC's and these claims are also seen to be substantially overlapping, specifically claims 33-42, 47 and 48 of the instant application and claims 33-40, 47 and 48 of copending application 09/067,337. The use of the same reactants and reaction conditions and procedural steps do indeed represent subject matter covered by both application's claims.

Ascertaining the differences between the prior art and the claims at issue

The difference between the subject matter of the instant 09/484,484 and copending application 09/67,337 is the scope of the variables intended to be attached to the core structures of the formulae. Specifically, the scope of the variables X¹ and Z are of differing scopes in the

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broadest claims, but the variables are commensurate in scope when dependent claim limitations to said variables are considered. The overlap is unmistakable and undeniable. To grant separate patents to this overlapping subject matter would provide applicant an opportunity to unfairly extend the patent grant for the subject matter sought.

Resolving the level of ordinary skill in the pertinent art

It would be obvious to one having ordinary skill in this art at the time the invention was made to compare the LPC compositions of the two applications as well as the process for preparing same and note that there is substantial overlap between these inventions necessitating some divergence in subject matter which would allow for independent and distinct inventions or an appropriate terminal disclaimer in both cases. The examiner is also curious as to whether or not there are additional applications filed drawn to compositions and processes which would overlap with the two applications before Examiner Wilson.

Considering objective evidence present in the application indicating obviousness or nonobviousness

In view of the overlapping subject matter, the evidence that these two applications are obvious over one another is clear. The use of the same formulae and modifying substituents as well as the same procedural steps clearly provides evidence of obviousness. Furthermore, there is

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no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over the Koster patent 5,198,540.

Claims are all drawn to liquid phase carriers (LPC) as indicated by the formulae represented in claims 6, 7, 9-11, 14-17, 20-22, 25, 26, 29, 31, 32, 45 and 49. Claims 39, 40, 47 and 48 of the 09/484,484 application are drawn to a method for solution phase biopolymer synthesis using a LPC compound.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Koster discloses compositions of matter which are liquid phase carriers, see column 1, line 29 through column 3, line 51. Note the correlative structure of the LPC of Koster as compared with the variable structure set forth in the instant claims, see carriers of claim 1. The compounds of Koster include LPCs possessing two to four points of attachment, which overlaps with applicant's optional number of points of attachment which include 3 to 6 points of attachment. The overlap is undeniable. The process claims of the Koster patent do indeed render applicant's claimed methods *prima facie* obvious. Equation 1 in column 10 provides the general procedural mechanism instantly claimed for preparing a biopolymer using a LPC. It is well established in patent law that use of a known member of a class of materials (LPC's in the instant case) in a process to produce the expected product (oligonucleotide) or result (biopolymeric synthesis) is not patentable if other members of the class are known to be useful for the same purpose, even though the results are better than expected.

The prior art LPCs are seen to overlap with those instantly claimed, however, the examiner does not that there are some differences between the compounds claimed and those of the prior art. Specifically, the instantly claimed invention contains additional points of attachment for the LPCs claimed and intended for use in methods for producing biopolymers.

It would have been obvious to one having ordinary skill in this art at the time the invention was made to formulate LPCs with multiple points of attachment and variable structure, because the prior art discloses such LPCs. Further, the prior art establishes that it is well known in the art to use LPCs to prepare biopolymers, specifically oligonucleotides. Once the general reaction has been shown to be old (specifically the reaction of an LPC with a monomer to prepare a polymer),

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applicants bear the burden to present reason or authority for believing that a group on the starting material would take part in or affect the basic reaction and thus alter the nature of the product or the operability of the process and thus the non-obviousness of the method for producing it.

Applicant's arguments filed February 28, 2002 and the Supplemental Response and Declaration filed April 16, 2002 have been fully considered but they are not persuasive.

First, the Declaration does not show "...data comparing the yields of oligonucleotide synthesis using LPCs (plural) of the instant claims. This is a misrepresentation of what the Declaration actually provides. The Declaration provides data comparing LPC's of the prior art with two points of attachment with a single representation of an LPC of the invention, specifically d(5'-O-DMT-G^{ib}pA^{bz}pC^{bz}pG^{ib}pG^{ib}pC^{bz}pC^{bz}pA^{bz}pG^{ib}pT)₃-Aryl-LPC.

Second, the Declaration provides a comparison of yields, but the examiner cannot determine whether the reaction conditions for the oligonucleotide synthesis using the LPC's of the prior art and the singular example provided in the Declaration as representative of the LPCs instantly claimed were indeed used in methodological procedures the skilled artisan would consider correlative and sufficient for a side-by-side analysis. No data or reaction conditions showing a true side by side comparison is seen in the Declaration of April 16, 2002.

Third, the examiner directs applicant to their admission that the prior art contemplates LPC's with two to four points of attachments, which overlap with applicant's assertion of points of attachment for the LPC set forth in the Declaration. Applicant admits on page 7, lines 7-8 of the Declaration, that one skilled in this art would be motivated from the 5,198,540 Patent of record to use an LPC with three points of attachment (as seen in their example), as well as four points of attachment, as instantly claimed. Maybe a better example for comparison would have been LPCs as instantly claimed which have three and four points of attachment correlative to those of the prior art with overlapping numbers of points of attachment, since the prior art

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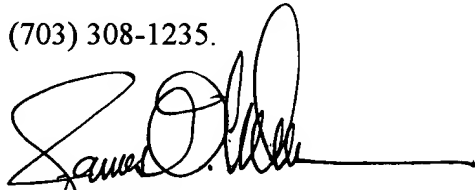
appears to indicate such compounds would be expected to succeed as LPCs in oligonucleotide synthesis. The overlap is clear and relevant to the teachings which indeed render applicant's compounds prima facie obvious for the reasons of record.

A claim to the specific LPC used in the oligonucleotide production data comparison with the prior art LPCs of the 5,198,540 Patent set forth in the properly executed Declaration of 4/16/02 might obviate the rejection of record under 35 USC 103. The examiner views applicant's arguments as indicative of the unpredictable nature of the structural variations in the LPCs claimed and as instantly claimed, and still maintains that the representations set forth in the Declaration are not sufficient to obviate the 103 rejection of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James O. Wilson, Primary Examiner in Art Unit 1623 whose telephone number is (703) 308-4624. The examiner can normally be reached on Monday-Friday from 10:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached on (703) 308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



JAMES O. WILSON
PRIMARY EXAMINER
Art Unit 1600